

REMARKS

Further to the Office Action dated September 1, 2004, claims 58-67 are currently under examination in the Application. By the above amendment, claim 58 has been canceled and claims 64 and 65 have been amended. Claim 65 has been amended to recite "increases", correcting the grammatical error as requested by the Examiner. With regard to the negative limitation recited in amended claim 64, Applicants submit, as discussed further below, that it was decided in *In re Johnson* that the use of negative provisos to excise a species disclosed in the prior art from the scope of a claimed genus is permissible. *See, In re Johnson*, 558 F.2d 1008, 194 U.S.P.Q. 187 (C.C.P.A. 1977). Support for the amendment can be found throughout the application as filed, for example, at page 18, lines 4-12 and page 19, lines 2-5. The above amendment is not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application. No new matter has been added.

Claim Rejections – 35 U.S.C. § 101

Claim 58 stands rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claim 32 of prior U.S. Patent No. 6,329,422.

Without acquiescing to the Action's rejection, Applicants have canceled claim 58 without prejudice. Applicants reserve the right to pursue the subject matter removed by this amendment in a related divisional, continuation and/or continuation-in-part applications.

Claim Rejections – Nonstatutory double patenting

Claims 59-63 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 32 of U.S. Patent No. 6,329,422. In particular, the Action contends that the flavones or isoflavones set forth in claims 59-63 of the instant application are species of the generic flavones/isoflavones set forth in claim 32 of the 6,329,422 patent. Accordingly, the Action asserts that they are anticipated as species of

that genus and the motivation to use them in the composition is still retained as they are recognized as capable of stimulating chloride secretion.

Applicants respectfully request that the rejection be held in abeyance until allowance of the instant application. While in no way admitting that claims 59-63 are obvious over or anticipated by the claims of U.S. Patent No. 6,329,422, at such time as the claims of the instant application are otherwise deemed by the PTO to be in condition for allowance, Applicants will consider filing a terminal disclaimer in the instant application.

Claims Rejections – 35 U.S.C. § 112, second paragraph

Claims 58-63 and 65 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential elements, such omission amounting to a gap between the elements. The Action contends that the omitted elements are the compounds that increase expression or trafficking of a CFTR.

Applicants respectfully traverse the rejection and submit that the test for definiteness under 35 U.S.C. § 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). Applicants assert that no essential elements are omitted from the claims and that the skilled artisan would readily understand the presently claimed invention when read in light of the specification. The specification as filed clearly describes a variety of compounds that increase expression or trafficking of a CFTR, for example at page 14, lines 11-30. Accordingly, the skilled artisan would readily understand the present claims in view of the general knowledge of the art and the teachings of the specification and further, would easily be able to identify compounds that increase expression or trafficking of a CFTR using techniques known in the art and described in the specification as filed, for example, at page 14, lines 26-30. Therefore, Applicants submit that the instant claims satisfy the requirements under 35 U.S.C. § 112, second paragraph and respectfully request withdrawal of the rejection.

Claims Rejections – 35 U.S.C. § 102

Claim 64 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Lyubenko et al., Abstract of RU 2,008,015, Derwent WPI Acc. No. 94-277493, February 28, 1994. The Action alleges that the cited reference teaches quercetin in combination with ascorbic acid.

Without acquiescing to the rejection, Applicants have amended claim 64 to recite the negative proviso “wherein said composition does not consist essentially of quercetin in combination with ascorbic acid. In this regard, Applicants submit, as noted above, that it was decided in *In re Johnson* that the use of negative provisos to excise a species disclosed in the prior art from the scope of a claimed genus is permissible. In *In re Johnson*, the applicants claimed a genus of certain thermoplastic polymers and, during prosecution, amended the claims to exclude several known prior art species that fell within the claimed genus. In reversing the Board’s decision that no basis existed in the application for the “limited genus” claimed by the applicants, the CCPA held that:

“The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of § 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute.” *Id.* at 196.

The CCPA further noted that the “specification, having described the whole, necessarily described the part remaining” and that the applicants “are merely excising the invention of another, to which they are not entitled, and are not creating an ‘artificial subgenus’ or claiming ‘new matter’”. *Id.* at 196.

Similarly, in the present application, Applicants have merely amended the claims in order to advance prosecution to exclude a species allegedly disclosed in the prior art from a genus which is fully supported in the specification (for example, see page 18, lines 4-12 and page 19, lines 2-5).

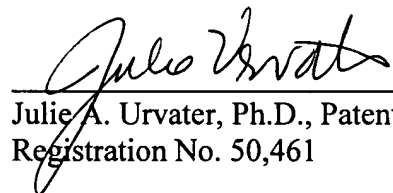
Applicants submit that the claims as amended are not anticipated by the cited art and respectfully request withdrawal of the rejection.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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